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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,032	02/21/2002	William W. Schlaepfer	PENN-0788	2903

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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,032	SCHLAEPFER ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Claims 1 and 2 are pending in the instant application.

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The "Request under 37 CFR § 1.821(e)" filed February 21, 2002 states that a paper copy of the Sequence Listing is included in the originally-filed specification of the instant application. However, no paper copy of the Sequence Listing is present in the case.

Specification

The disclosure is objected to because of the following informalities:

As mentioned above, a paper copy of the Sequence Listing is not present in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, for reasons of record, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 2 is directed to a method of identifying specific components of RNA-protein complexes that can be used to prevent motor neuron degeneration.

The claims require contacting a first population of neuronal cells or tissues with a candidate component of an RNA-protein complex. Since a "component of an RNA-protein complex" must be either RNA or protein, it is evident that the candidate agents are either RNA or protein. However, the specification does not offer any guidance as to how contacting a cell or tissue with RNA or protein would allow the RNA or protein to get inside the cell where it can interact with the neuropathic element (i.e., the NF-L mRNA). Thus, one of skill in the art would not know how to successfully carry out the claimed method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in its recitation of "neuropathic effects" because the claimed method can be carried out either *in vitro* or *in vivo*, but the specification does not define the term "neuropathic effects" in the *in vitro* context. Thus, one skilled in the art would not know what types of in vitro measurements would constitute "neuropathic effects." The metes and bounds of the claim are not clearly set forth.

Claim 2 is indefinite in its recitation of "where the candidate component of a RNA-protein complex has been expressed" because in part (b) the candidate component is contacted with the cells or

tissues, but it is not **expressed.** Thus, when the phrase "has been expressed" appears, it is confusing because there is no recitation earlier in the claim involving **expression** of the candidate component.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Canete-Soler et al. (1998, J. Biol. Chem. 273(20): 12655-12661).

Claim 1 is directed to a neuropathic RNA element that produces motor neuron degeneration comprising a wild-type neurofilament L mRNA.

Canete-Soler et al. (1998) disclose a wild-type neurofilament L mRNA. The reference discloses that levels of neurofilament (NF) expression are regulated by altering mRNA stability and that stability determinants are present in the 3'-coding region and 3'-untranslated region (3'-UTR) of the NF light subunit (NF-L) transcript (see abstract). The abstract states "[t]his study characterizes the ribonucleoprotein complexes that bind to the NF-L mRNA when cytoplasmic brain extracts are incubated with radioactive probes." Figure 1 shows a schematic diagram of the RNA probes used in the study in relation to the mouse NF-L cDNA.

Thus, the claimed invention is disclosed in the prior art.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Canete-Soler et al. (1998, J. Biol. Chem. 273(20): 12650-12654).

Canete-Soler et al. (1998) disclose the wild-type mouse neurofilament L mRNA.

Thus, the claimed invention is disclosed in the prior art.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Soppet et al. (1991, J. Neurosci. Res. 30:42-46).

Soppet et al. (1991) disclose the isolation of the rabbit NF-L cDNA. Since cDNA molecules are synthesized using the mRNA molecule as the template, the reference thereby discloses the rabbit NF-L mRNA. The reference further discloses that the polyadenylated RNA, which is used as the template for cDNA synthesis, was isolated from rabbit brains (see p. 42, column 2, paragraph 3). cDNA was synthesized from rabbit brain poly-A RNA and a cDNA library was constructed. A 2.0 kb cDNA corresponding to rabbit NF-L mRNA was isolated and sequenced. The nucleotide sequence of the 2.0 kb rabbit NF-L cDNA is disclosed in Figure 4.

Thus, the claimed invention is disclosed in the prior art.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bergeron et al. (1993, J. Neuropathol. Exp. Neurol. 52:278).

Bergeron et al. disclose human NF-L mRNA, as well as wild-type mouse NF-L mRNA.

Thus, the claimed invention is disclosed in the prior art.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sasahara et al. (1996, J. Biol. Chem. 271(42): 25950-25957).

Sasahara et al. (1996) disclose wild-type mouse NF-L mRNA. The reference further discloses that okadaic acid treatment reduced the stability of the 3.5- and 2.3 kilobase NF-L mRNAs. The study

results demonstrate that okadaic acid treatment inhibits the differentiation-dependent increase in NF-L gene expression by destabilizing its mRNA.

Thus, the claimed invention is disclosed in the prior art.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (1992, J. Biol. Chem. 267(34): 24596-24600).

Schwartz et al. (1992) disclose wild-type rat NF-L mRNA. The reference further discloses that actinomycin prevents the destabilization of neurofilament mRNA in primary sensory neurons. The reference proposes that putative stabilizing factors are able to prevent degradation of NF transcripts in intact neurons, but not in axotomized or cultured neurons (see abstract).

Thus, the claimed invention is disclosed in the prior art.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Paterno et al. (1997, Molecular Brain Research 49: 247-254).

Paterno et al. (1997) disclose wild-type NF-L mRNA present in P19 embryonal carcinoma cells.

Thus, the claimed invention is disclosed in the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The central official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Dianiece Jacobs, whose telephone number is (571) 272-0532.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: The specification and/or figures must be amended to identify all disclosed sequences by their sequence identifier (i.e., SEQ ID NO), in accordance with 37 CFR 1.821(d).

Applicant Must Provide:

☐ An **initial** computer readable form (CRF) copy of the "Sequence Listing".

☒ An **initial** paper copy of the "Sequence Listing", **as well as an amendment directing its entry into the specification.**

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:
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